

REMARKS

1. Interview Summary Record

We thank the Examiner for according Counsel a telephonic interview on August 29.

The Examiner agreed that if group I claims were converted into composition claims dependent on claim 32, they would be rejoined, and we noted that the appropriate species elections were already made in section 5 of the January 18, 2008 Election with Traverse.

We also discussed the prior art and double patenting rejections.

Finally, the Examiner was of the opinion that Schemes 1A, 1B, 2A and 2B should be converted into Figures. We didn't discuss scheme 3 but we assumed it should be handled the same way.

2. Election (OA §2)

2.1. Our election of Group II is acknowledged by the Examiner. The Frankel reference cited by the Examiner in support of imposing the restriction of the claims no longer seems to play a role in the Examiner's evaluation of our claims. However, the Examiner now seems to maintain the imposed restriction based on the contents of Grøtli (US 6,642,334). We do not agree with the Examiner's interpretation of Grøtli, see section 5 below.

2.2. Claim 1 has been cancelled, and claims 2-31 amended to transform them into composition claims dependent on examined group II claim 32. Hence, these claims should be rejoined. Species elections relative to these claims were made in section 5 of the January 18, 2008 election with traverse.

3. Conformance of Drawings and Description (OA §8-9)

3.1. In response to OA §8, descriptions of Scheme 1A (now Fig. 21A), 1B (Fig. 21B), 2A (Fig. 22A), 2B (Fig. 23A) and Figs.

5a and 5b have been added to the specification.

3.2. In response to OA §9, we submit a substitute sheet 30/34, which now is identified as "FIG. 15"

4. Objections (OA §11, 12)

We have amended claim 32 as suggested, and cancelled claim 41.

5. Definiteness (OA §13-14)

5.1. The Examiner questioned antecedent basis for "each beaded polymer matrix" (claim 38). This has been changed to "each bead".

5.2. The Examiner questioned antecedent basis for "spatial position of particles" (claim 42). Base claim 32 recites that the bead comprises from 3 to 10 particles. These particles necessarily must have a "spatial position" within the bead and present PTO practice is not to apply "antecedent basis" concepts so excessively as to require explicit, verbose recitation of plainly inherent features e.g., you can refer to a side of a building without first reciting "having at least one side".

Nonetheless, we have further amended claim 32 to recite that the particles have predetermined spatial positions within the bead, which collectively serve to identify the bead.

6. Prior Art Issues (OA §16)

The following prior art rejections have been made:

- (1) claims 32, 38-42, as anticipated by Miranda (OA §17);
- (2) claims 32, 38-42, as anticipated by Strathmann (OA §18);
- (3) claims 32, 38-42, as anticipated by Grötli under 102(e) (OA §19);
- (4) claims 32-33, 38-42, as obvious over Grötli and Seul under 102(e)/103 (OA §21).

We respectfully traverse.

The following references have been cited by the Examiner in the outstanding OA:

- Miranda et al. 2002, J. Comb. Chem.
- Strathmann et al. 2000, Appl Microbiol Biotechnol
- US 6,642,334 (Grötli)
- US 7,156,315 (Seul)

We believe that the Examiner has not understood our invention and is evaluating incorrectly the contents of the above-cited references. Some of the references do cite "beads" and "particles", but none of the references cited by the Examiner discloses the invention covered by our amended claim 32:

A composition comprising a plurality of different, spatially encoded beads, each bead (beaded polymer matrix) comprising

- a plurality of spatially immobilised particles held in a polymer matrix, the particles having predetermined spatial positions which collectively identify the bead,

-wherein each particle is individually detectable,

-wherein the encoded bead has a diameter of from 0.5 millimeter to less than 2.0 millimeter and comprises from 3 to not more than 10 particles,

-wherein the diameter of the particles is less than 30 micrometer.

It is evident that the term "beaded polymer matrix" refers

to a single bead, see page 1, lines 12-13, and each bead comprises a plurality of spatially immobilized particles, see lines 15-20 (which are not be confused with the beads). The particles are also termed microbeads, see page 6, lines 27-28.

Accordingly, the composition of claim 32 comprising a plurality of the above-cited beads is not anticipated by any of the references cited by the Examiner.

We note that the novelty of claim 33 is acknowledged by the Examiner.

6.1. Anticipation by Miranda (OA §17)

The Miranda reference is directed to Morten Meldal's SPOCC-194 resin and Morten has not disclosed an "encoded bead" aspect in the Miranda reference. The Miranda reference is merely directed to the synthesis of an "ordinary" resin - i.e. a resin which does not have spatially immobilised and individually identifiable particles embedded therein.

The Examiner seems to believe that the white sections on the surface of the resin beads illustrated in Miranda Fig. 2 constitute a plurality of individually detectable, spatially immobilised particles. This is not correct. The white sections appearing in Fig. 2 are due to reflections conceivably caused by multiple sources of illumination used for the microscopical analysis. The fact that the white sections result from a reflection of a light source is evidenced by the obvious similarity of the "pattern" formed by the white sections on each bead. Individually detectable, spatially immobilised particles do not display such a "pattern".

Moreover, even if the Examiner believes that there is a possibility that the white sections are beads, that is inadequate. The Examiner is inferring that the Miranda beads inherently possess the claimed feature (particles) from an explicit feature (their appearance in Fig. 2).

The general rule concerning inherent anticipation is that the allegedly inherent feature must be certain to be present in view of the explicit features. See Ex parte Levy, 17 USPQ2d 1461, 1464 (BPAI 1990) ("inherent characteristic necessarily flows" from prior art teachings); Glaxo Inc. v. Novopharm Ltd., 29 USPQ2d 1126 (EDNC 1993), aff'd 34 USPQ2d 1565 (Fed. Cir. 1995) (allegedly inherent result must "invariably" happen); Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc., 32 USPQ2d 1017, 1020 (Fed. Cir. 1994) (that a thing "may result" is insufficient); Motorola, Inc. v. Interdigital Technology Corp., 930 F. Supp. 952, 970 (D. Del. 1996); Marion Merrell Dow Inc. v. Geneva Pharmaceuticals, 33 USPQ2d 1673, 1677 (D. Col. 1994); Hughes Aircraft Co. v. United States, 8 USPQ2d 1580, 1583 (Claims Ct. 1988) (in anticipation-by-inherency cases, the element must "flow undeniably and irrefutably from the express disclosures"); Ethyl Molded Products Co. v. Betts Package, Inc., 9 USPQ2d 1001, 1032-3 (E.D. Ky. 1988) (doctrine requires "certainty"; "probabilities are not sufficient"); Phillips Petroleum Co. v. U.S. Steel Corp., 6 USPQ2d 1065, 1076-77 n. 12 (D. Del. 1987), aff'd 9 USPQ2d 1461 (Fed. Cir. 1989) ("anticipation...cannot be predicated on mere conjecture").

Applicant having demonstrated that an alternative explanation for the white sections exist - they are reflections of ambient light -- the examiner must either find conclusive evidence that they are particles, or withdraw the holding of inherent anticipation.

Accordingly, we do not agree with the Examiner's assertion that the beads illustrated in Fig. 2 of Miranda are "individually identifiable". There is no teaching in Miranda of how to produce a resin comprising (embedded therein) a plurality of individually detectable, spatially immobilised particles - for the simple reason that the Miranda reference is not directed to such a resin. As the resin synthesised in Miranda does not contain any

individually detectable, spatially immobilised particles, Miranda cannot anticipate the present invention.

Furthermore, most, if not all, of the beads illustrated in Fig. 2 have more than 10 white sections - thereby effectively falling outside the scope of the claims - even by the Examiner's incorrect assessment of the term "particle".

Moreover, there is no teaching in Miranda of the diameter of the synthesized beads.

In conclusion: Miranda does not anticipate claims 32 and 38 to 42.

6.2. Anticipation by Strathmann (OA §18)

Strathmann teaches homogeneous agarose beads having a diameter of 50-500 microns (0.5 millimeters) (see abstract, line 5) and super porous agarose beads having a mean diameter (260 microns, see abstract line 6).

The Examiner argues that the bacteria embedded in the homogeneous or superporous beads qualify as "particles" within the meaning of the present claim, and Fig. 4 shows that there are some bacteria internal to the homogeneous bead, and many more internal to the superporous bead. However, that is insufficient for anticipation.

First, neither bead satisfies the bead diameter limitation of claim 32. In the case of the homogeneous beads, we have "touching" ranges (50-500 microns versus 5000-2000 microns). According to MPEP 2131.03(II), prior art which teaches a range touching, or even slightly overlapping, a claimed range anticipates only if the prior art teaches the claimed range with sufficient specificity. In Atofina v. Great Lakes Chem. Corp., 78 USPQ2d 1417, 1423 (Fed. Cir. 2006), it was held that the reference range 100-500 did not anticipate the "slightly" overlapping range 150-350.

In the case of the superporous beads, all we know is the

mean diameter (260 microns), which is clearly outside the claimed range.

The Examiner argued that the superporous beads inherently have a maximum diameter of 520 microns, exceeding the claimed lower limit of 500 microns by virtue of having a mean diameter of 260 microns. However, there is no evidence of record that the maximum diameter is twice the mean diameter.

Rather, the Examiner is inferring that the range of bead diameters inherently exceeds 500 microns from the explicit teaching of their mean diameter. However, there are many possible ranges which all have the same mean. Hence, as a matter of law, the examiner has failed to establish inherent anticipation.

Moreover, even if it were proven that Strathmann's superporous beads reached a diameter of 520 microns, that would appear to be merely a "slight overlap" with the claimed 500-2000 microns, without teaching the "overlap" (500-520 micron) beads with sufficient specificity to anticipate per MPEP 2131.03(II).

Strathmann's beads also clearly fail to satisfy the particles-per-bead limitation of claim 32. Claim 32 recites 3-10 particles per bead. However, there are many more than 10 bacteria in even the homogeneous bead of Strathmann Fig. 4A, let alone the superporous bead of Strathmann Fig. 4B.

In conclusion: Strathmann does not anticipate claims 32 and 38 to 42.

6.3. Anticipation by Grötli (US 6,642,334) (OA §19)

The '334 patent is directed to the synthesis of an "ordinary" resin - i.e. a resin which does not have spatially immobilised and individually identifiable particles embedded therein.

The Examiner seems to believe that the white sections on the surface of the resin beads illustrated in Grötli Figs. 1A, 1B and

1C constitute a plurality of individually detectable, spatially immobilised particles. This is not correct. The white sections appearing in Figs. 1A, 1B and 1C are due to reflections conceivably caused by multiple sources of illumination used for the microscopical analysis. The fact that the white sections result from a reflection of a light source is evidenced by the obvious similarity of the "pattern" formed by the white sections on each bead. Individually detectable, spatially immobilised particles do not display such a "pattern".

Accordingly, we do not agree with the Examiner's assertion that the beads illustrated in Figs. 1A, 1B and 1C of the '334 patent are "individually identifiable". There is no teaching in the '334 patent of how to produce a resin comprising (embedded therein) a plurality of individually detectable, spatially immobilised particles - for the simple reason that the '334 patent is not directed to such a resin.

Most, if not all, of the beads illustrated in Grötli Figs. 1A, 1B and 1C have more than 10 white sections - thereby effectively falling outside the scope of the claims even by the Examiner's incorrect assessment of the term "particle".

In conclusion: The '334 patent does not anticipate claims 32 and 38 to 42.

6.4. Non-obviousness over Grötli and Seul

Grötli was previously discussed. Seul describes a method and apparatus for the manipulation of colloidal particles. A set of colloidal particles may be captured, and arrays formed on the surface of an electrode, as shown in the cited Figures, e.g., 2A-2D. These arrays are responsive to the electric field, as taught at col. 6, lines 41-44.

Seul teaches a simple array of "colloidal particles", but these particles, if deemed equivalent to the claimed beads, are not themselves composed of microbeads. Thus, they lack the

hierarchical structure required by the claims. Nor can Seul's array be deemed equivalent to the claimed bead (so Seul's particles are equivalent to microbeads), since the colloidal particles in Seul's array clearly are not spatially fixed, and in any event, an array on a plate is not a bead.

The combination of the '334 and '315 patents thus does not arrive at the claimed invention as neither of the patents disclose a bead comprising a plurality of individually detectable, spatially immobilised particles - let alone from 3 to 10 individually identifiable, spatially immobilised particles each having a diameter of less than 30 micrometer.

Neither of the above-cited patents motivate the skilled person to modify the prior art and arrive - with a reasonable expectation of success - at the claimed invention.

7. Double Patenting (OA §§22-24)

Claim 32 and 38-41 stand provisionally rejected for obviousness-type double patenting over copending 11/631,181 (OA §23) and 10/566,757 (OA §24). We respectfully request that these provisional rejections be held in abeyance until (A) they are the only issues remaining in this case or (B) one of the reference applications is allowed, at which time applicants can determine whether the double patenting rejection should be overcome by (1) argument distinguishing the then-pending claims of this case from the then-allowed claims of the reference case, (2) amending the claims in this case to distinguish the reference claims, or (3) filing a terminal disclaimer. It is noted that since this case is the senior case, if situation (A) applies, the rejection would be withdrawn pursuant to MPEP 804(I)(B)(1).

8. Miscellaneous

We enclose a courtesy copy of the IPE report. It shows that the IPEA accepted the arguments which we made in the response to

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first written opinion (copy filed March 28, 2005) distinguishing the prior art cited in the First Written Opinion and the international search report (copy filed March 28, 2005).

The references cited in the IPER are all of record here:

| <u>FWO ID</u> | <u>Reference</u> | <u>2006 IDS</u> |
|---------------|-------------------------|-----------------|
| D1 | WO 98/47838 | AG |
| D2 | US2002/071121 | AD |
| D3 | Trau 2001 | AW |
| D4 | WO 99/59011 | AH |
| D5 | Lawandy US 5,434,878 | AA |
| D6 | WO 00/21658 | AI |
| D7 | Fodor US 6,252,236 | AE |
| D8 | WO 00/63419 | AK |

Respectfully submitted,

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Enclosures

- replacement sheets 1/34-4/34, 11/34, 30/34
- IPE report

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